Center for Clinical and Translational Science

CONSENTING NOTE INSTRUCTIONS

PURPOSE

This tool is intended to assist the user in the consent process by providing a framework for documentation of the consent discussion and process in the participant files.

HOW TO USE

- Customize the consenting note template for your study.
    - Some items to consider:
        - Additional detail on the type of participant consent/assent/assent script combination used
        - Additional detail on the consenting process if using a Foreign Language (translated) participant consent/assent/assent script such as:
            - The form used was an IRB approved, certified translation
            - A translator was present or utilized during the consent process
            - The translator signed the consent form as a witness
            - Which forms were provided for the participant to take with them – i.e. the participant was assented in English, the parent/LAR was consented in Spanish, the participant received copies of the signed forms as well as an unsigned copy of the assent form in Spanish for reference.
        - Additional detail on the consenting process if the participant is illiterate
            - The consent form was read to the participant and by whom
            - A witness was present, and their signature was included on the consent form
- Determine where to place the consent note in the participants file
    - Electronic file – AEHR
    - Participant Binder - with the consent/assent/assent script
- Establish a plan for use, train study personnel in that plan
- Use per plan, complete periodic reviews to confirm that the process is taking place as planned
- Revise the process as needed

GOOD PRACTICE RECOMMENDATIONS

- Use the tool for initial consent as well as throughout the study, as consent forms are updated and participants are re-consented.